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Frank C. Eisenschenk, Ph.D., Patent Attorney

INFORMATION DISCLOSURE STATEMENT Examining Group 1761 Patent Application Docket No. SER-111 Serial No. 10/582,027

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant** 

Maria Dorly Del Curto

Serial No.

10/582,027

Filed

June 8, 2006

Conf. No.

1354

For

Stabilized Interferon Liquid Formulations

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, Applicant has not submitted a copy of the U.S. patents cited on attached Form PTO/SB/08 pursuant to 37 C.F.R. 1.98(a)(2)(ii).

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicant respectfully asserts that the substantive provisions of 37 C.F.R. §§ 1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.

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Attachments: Form PTO/SB/08; copies of references cited therein.

OIPE 428

PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for fo	orm 1449A/PTO			Complete if Known		
			.DE	Application Number	10/582,027	
	ATION DISC IENT BY APF			Filing Date	June 8, 2006	
SIAIEW	IENI DI APP	LIG	AIN I	First Named Inventor	Maria Dorly Del Curto	
(	use as many sheets	as nec	essary)	Art Unit		
				Examiner Name		
Sheet	1	of	2	Attorney Docket Number	SER-111	

	U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	U1	US-5,997,856	12-07-1999	Hora <i>et al</i> .	All	
	U2	US-6,582,728	06-24-2003	Platz et al.	All	
	U3	US-				
	U4	US-				
	U5	US-				
	U6	US-				
	U7	US-				
:	U8	US-				
	U9	US-				

FOREIGN PATENT DOCUMENTS							
		Foreign Patent Document	Dublication Date	Name of Detector of	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
Examiner Initials*	Cite No. 1	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		T <sup>6</sup>	
	F1	WO 03/002152 A2	01-09-2003	Maxygen APS	All		
	F2	WO 90/03784 A1	04-19-1990	Cetus Corporation	All		
	F3	WO 2005/117949 A1	12-15-2005	Ares Trading S.A.	All		
	F4		-				
	F5						
	F6						
	F7						

Examiner	Date
Signature	Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	Cubalitus	te for form 1449B/PTC			Complete if Known		
		RMATION D		OSLIDE	Application Number	10/582,027	
					Filing Date	June 8, 2006	
1	SIA	<b>TEMENT BY</b>	AP	LICANI	First Named Inventor	Maria Dorly Del Curto	
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(use as many sheets as necessary)		Examiner Name					
	Sheet	2	of	2	Attorney Docket Number	SER-111	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R1	HULTGREN, C. et al. "The Antiviral Compound Ribavirin Modulates the T Helper (Th) 1/Th2 Subset Balance in Hepatitis B and C Virus-Specific Immune Responses", <i>Journal of General Virology</i> , 1998, pp. 2381-2391, Vol. 79.	
	R2	MARK, D. F. et al. "Site-Specific Mutagenesis of the Human Fibroblast Interferon Gene", Proc. Natl. Acad. Sci. USA, September 1984, pp. 5662-5666, Vol. 81.	
	R3	RUBINSTEIN, S. et al. "Convenient Assay for Interferons", Journal of Virology, February 1981, pp. 755-758, Vol. 37, No. 2.	
	R4	BREWSTER, M. E. <i>et al.</i> "Use of 2-Hydroxypropyl-β-cyclodextrin as a Solubilizing and Stabilizing Excipient for Protein Drugs", <i>Pharmaceutical Research</i> , 1991, pp. 792-795, Vol. 8, No. 6.	
	, R5	ARAKAWA, T. et al. "Factors affecting short-term and long-term stabilities of proteins" Advanced Drug Delivery Reviews, 2001, pp. 307-326, Vol. 46, Nos. 1-3.	
·	R6	IRIE, T. et al. "Cyclodextrins in peptide and protein delivery" Advanced Drug Delivery Reviews, 1999, pp. 101-123, Vol. 36.	
	R7	U.S. Application Serial No. 11/597,987 (claims only), filed November 30, 2006 (not yet published), pp. 1-4.	
	R8		
:	R9		
	R10		
	R11		
	R12	•	

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Examiner	Date
Signature	Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

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